K103445

AUG 1 2 2011

GE Healthcare
510(k) Premarket Notification Submission

Section 5: 510(k) Summary

Brivo XR385

AUG 12 2011 K103448

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 19, 2010
Submitter:	GE Healthcare, (GE MEDICAL SYSTEMS, LLC) 3000 N. Grandview blvd. W-709
Primary Contact Person:	John L. Schmidt Regulatory Affairs Leader-X-Ray GE Healthcare, (GE MEDICAL SYSTEMS, LLC) TEL: (262) 548-4964 FAX: (262) 548-2721 e-mail: John.L.Schmidt@ge.com
Secondary Contact Person:	David Blonski Regulatory Affairs Director GE Healthcare, (GE MEDICAL SYSTEMS, LLC) 3000 N. Grandview blvd. (W-709) 262 513-4072 548-2721 e-mail: David.Blonski@ge.com
Device: Trade Name:	Brivo XR385
Common/Usual Name:	Digital Diagnostic Radiographic System
Classification Names:	Stationary X-Ray System (21CFR § 892.1680) and solid state x-ray imager (21CFR § 892.1650)
Product Code:	KPR and MQB
Predicate Device(s):	Stationary x-ray system MODEL: Silhouette VR (K982955) GE Tethered Portable Digital Radiographic Detector (K041922) Canon digital radiography CXDI-50G (K031447)
Device Description:	The Brivo XR385 Digital Diagnostic Radiographic system provides state of the art image quality, image manipulation, operator control, dose reporting and system maintenance. These features make this system easy to use and reliable while providing high quality radiographic images in a digital environment. The Brivo XR385 system configuration includes an integrated tube stand and patient support table with a floating table top, under-the-table high-voltage generator and power distribution unit, an X-ray tube assembly with dual focal spot X-

ray tube, a manual beam limiting device, a wall stand and a digital detector that captures radiographic images in digital form. The system also includes an acquisition and review workstation for image post-processing, short-term storage, and quick in-room viewing of images. Images may be transferred manually or automatically via a DICOM network for printing, long-term storage archive, and detailed review.

Intended Use: The Brivo XR385 Digital X-Ray System is intended for use on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Technology: The Brivo XR385 Digital Diagnostic Radiographic system employs the same construction of Silhouette VR Radiographic system: an integrated tube stand and patient support table with a floating table top, under-the-table high-voltage generator and power distribution unit, an X-ray tube assembly with dual focal spot X-ray tube, a manual beam limiting device, and a wall stand.

The Brivo XR385 also employs GE's patented digital detector that captures radiographic images in digital form. The digital detector design is the same as the GE Tethered Portable Digital Radiographic detector (also referred to as Trad) with the exception of the scintillator material changing from Csl to GdOS as is in the Canon digital detector CXDI-50G.

The system also includes an acquisition and review workstation for image post-processing, short-term storage, and quick in-room viewing of images.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Brivo XR385 and its applications comply with voluntary standards and related FDA guidance as detailed in Section 9, 17 and 12 of this premarket submission. The following quality assurance measures were applied to the development of the system:

Risk Analysis

Requirements Reviews

Design Reviews

Testing on unit level (Module verification)

Integration testing (System verification)

Performance testing (Verification)

Safety testing (Verification)

Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Brivo XR385, did not require clinical studies to support substantial equivalence.

Conclusion: After analyzing standards testing and bench data, it is the

conclusion of GE Healthcare that the Brivo XR385 is substantially equivalent to other marketed devices with similar indications for use and meeting the same standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. John L. Schmidt
Regulatory Affairs Leader-X-Ray
GE Healthcare
3000 N. Grandview Blvd.
WAUKESHA WI 53188

AUG 12 2011

Re: K103448
Trade/Device Name: Brivo XR385
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 30, 2011
Received: July 1, 2011

Dear Mr. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A

Device Name: Brivo XR385

Indications for Use:

The Brivo XR385 Digital X-Ray System is intended for use on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K103448